

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

INGENUS PHARMACEUTICALS,
LLC and LEIUTIS
PHARMACEUTICALS LLP,

Plaintiffs,

v.

NEXUS PHARMACEUTICALS, INC.,

Defendant.

Case No. 22-cv-2868

Judge Mary M. Rowland

MEMORANDUM OPINION AND ORDER

Plaintiffs Ingenuis Pharmaceuticals, LLP (“Ingenuis”) and Leiutis Pharmaceuticals LLP (“Leiutis”) have sued Defendant Nexus Pharmaceuticals Inc. (“Nexus”) for infringement of U.S. Patent No. 10,993,952 (the “952 Patent”). Nexus asserts a counterclaim for inequitable conduct alleging that during prosecution of U.S. Patent Application No. 15/551,507 (the “507 Application”), which matured into the 952 Patent, applicant Leiutis engaged in “a pattern of conduct of misrepresentations of material information.” [41] ¶ 25. Before the Court are the parties’ claim construction briefs and Plaintiffs’ motion for judgment on the pleadings [43]. For the following reasons, the Court adopts the constructions identified below, defers consideration of the claim term Defendant asserts is indefinite, and grants Plaintiffs’ motion for judgment on the pleadings.

I. Claim Construction

A. Legal Standard

The construction of a patent is a question of law for the Court. *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 387–88 (1996). The Court must discern the meaning of claim terms, which is “the ordinary and customary meaning ... that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc).

Claim construction begins by considering the words of the claim. *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1362–63 (Fed. Cir. 2014). As indicated, claim terms are generally given their ordinary and customary meaning, which is the meaning it would have to a person of ordinary skill in the field at the time of the invention. *Phillips*, 45 F.3d at 1312–13. The person of ordinary skill “is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.* at 1313. Other claims in the patent “can also be valuable sources of enlightenment as to the meaning of a claim term,” as claim terms “are normally used consistently throughout the patent.” *Id.* at 1314. Differences among claims may, in some situations, be a useful guide to determining the meaning of a particular term. *Id.*

“The claims, [however], do not stand alone.” *Id.* at 1315. They are part of a larger document, including the specification. *Id.* Thus claims “must be read in view

of the specification, of which they are a part.” *Id.* In some situations, the specification “may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Id.* at 1316. And in other situations, the specification may show a disclaimer of claim scope, which is likewise dispositive. *Id.* Generally, however, it is inappropriate to confine the claims to the specific embodiments of the invention described in the specification. *Id.* at 1323. That said, the distinction between using the specification to help interpret a claim and importing limitations from the specification into the claim “can be a difficult one to apply in practice.” *Id.*

In certain circumstances, a court may also rely on evidence extrinsic to the claim, “which ‘consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.’” *Id.* at 1317 (quoting *Markman*, 52 F.3d at 980). But extrinsic evidence is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* (cleaned up). It is only where the intrinsic evidence is ambiguous that a court may rely on extrinsic evidence to construe a claim term. *Id.*

B. Analysis

1. “ethanol content of about 70% to about 75%”

The parties proposed constructions are summarized in the chart below.

Claim Term	Nexus’s Proposed Construction	Plaintiffs’ Proposed Construction
“ethanol content of about 70% to about 75%”	“ethanol content of 70% to 75%”	No construction necessary.

The Court begins by examining the words of the claims and specification. “The word ‘about’ does not have a universal meaning in patent claims, and [its] meaning depends on the technological facts of the particular case.” *Cohesive Technologies, Inc. v. Waters Corp.*, 543 F.3d 1351, 1368 (Fed. Cir. 2008). The term “about 70% to about 75%” is recited in independent Claim 1 of the ’952 Patent, and by necessity, dependent Claims 2–3. The claims recite the ethanol amount as a percentage of total formulation weight, but do not otherwise provide a definition of the term. The term “about” appears not less than 16 times in the claims in addition to the two terms challenged by Nexus. Because it is legally presumed that the same terms appearing in different portions of the claims should be given the same meaning, the repeated use of “about” in other claims (referring to other formulation amounts) informs the construction of “about” in Claim 1. *See Phillips*, 415 F.3d at 1315.

In the specification, “about” is used to describe the solvent content of the formulation. The ’952 Patent states “[t]he quantity of solvents ranges from *about* 40-99% by weight of the composition.” J.A. 3, col. 3, ll. 29–31 (emphasis added). Below that statement, the patent describes the preferred embodiment of the invention as having as a solvent ethanol (20-98%), while the most preferred embodiment of the invention as having as a solvent ethanol (40-92%). J.A. 3, col. 3, ll. 49–67. The Examples disclose ethanol amounts (based on total formulation weight) of 75.9% (Ex. 1), 74.81% (Ex. 2), and 70.58% (Ex. 6). This provides further support for “about” permitting a claim scope that goes beyond the fixed endpoints of 70% and 75% as proposed by Nexus.

As to the prosecution history, Nexus contends that limiting amendments support its construction. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 735 (2002) (“the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter”). The original patent application included a claim where the ethanol content was a range of “20-98%,” which was rejected by the examiner, and the applicants cancelled that claim. [51] at 7; [51-1]. After new claims and additional rejections, Plaintiffs’ patent prosecution counsel submitted amended claims that claimed an ethanol content of “about 69.5%-about 76.5%.” [51-5] at 2. The applicants argued that their then-proposed range of 69.5% to 76.5% was supported by the specification, however the examiner disagreed, noting that a concentration range of ethanol from 69.5% to 76.5% did not find support in the specification. [51-6] at 1. In response, the applicants filed a supplemental amendment dated March 23, 2021, with a range of “ethanol content of about 70% to about 75%.”

Nexus argues that Plaintiffs knowingly surrendered ethanol content below 70% and above 75% to gain allowance of the ’952 patent. *See Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136–37 (1942) (holding that relinquishments of claim scope made by an applicant to overcome an examiner’s rejection must be strictly construed against the patent holder in subsequent infringement litigation). Nexus is correct that in an interview “the examiner noted that the ethanol concentration range of 69.5% to 76.5%” and the PEG and PG concentration ranges of 3.25% to 8.85% in

claim 46 “do not find support in the specification.” J.A. 564. The applicants proceeded to amend the claims as follows:

Claimed Ingredient	Before Amendment	After Amendment
Ethanol content	about 69.5% - about 76.5%	about 70% - about 75%
PEG content	about 3.25% to about 8.85%	about 3.4% to about 8.8%
PG content	about 3.25% to about 8.85%	about 3.4% to about 8.8%

However, the Court cannot “rely on the prosecution history to construe the meaning of the claim to be narrower than it would otherwise be unless a patentee limited or surrendered claim scope through a *clear and unmistakable disavowal.*” *3M Innovative Properties v. Tredegar Corp.*, 725 F.3d 1315, 1322 (Fed. Cir. 2013) (emphasis added). The fact that the applicants amended the claim does not mean that they “clearly and unmistakably” disclaimed or disavowed any scope of the claimed range, particularly that which is accorded by the term “about” at each end of the range. Moreover, the examiner allowed the claims and stated that formulations of Example 2, Example 6 and the 90:5:5 (ethanol:PEG:PG) example described in the January 2021 declaration were “all encompassed by the instant claims” and that “[t]he results presented in Tables, pages 4- 5, Declaration of 15 January 2021, show unexpected stability with the instantly claimed formulations, compared to that achieved with formulations taught by the prior art by Palepu and Alam.” J.A. 558–59. Therefore, the examiner acknowledged that the 90:5:5 formulation—containing 69.81% ethanol—was covered by the claims she found patentable over the prior art. Put differently, the same formulation the patent examiner stated was covered by the instant claims would not be covered under Nexus’s proposal. Therefore, Nexus’s

proposed construction improperly adds meaning that is not found in the claims and is not required by the specification or prosecution history.

Overall, the claim language, specification, and prosecution history does not compel a deviation from the ordinary meaning of the word “about” and the Court gives the term “about” its ordinary meaning of “approximately.” *See Merck & Co. v. Teca Pharms. USA, Inc.*, 395 F.3d 1364, 1369–72 & n. 7 (Fed.Cir.2005). Accordingly, the Court construes “ethanol content of about 70% to about 75%” as “ethanol content of approximately 70% to approximately 75%”.

2. “cyclophosphamide in a concentration of about 12% to about 23%”

The parties proposed constructions are summarized in the chart below.

Term	Nexus's Proposed Construction	Plaintiffs' Proposed Construction
“cyclophosphamide in a concentration of about 12% to about 23%”	“cyclophosphamide in a concentration of 12% to 23%”	No construction necessary.

First, beginning with the language of the claims, there are over a dozen instances of “about” recited in the claims. None are proposed for construction, or for elimination entirely (other than the disputed terms), or to have a meaning other than their commonly accepted meaning. *Phillips*, 415 F.3d at 1314 (“Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms . . . Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.”). The

term “about” should be understood consistently throughout the claims consistent with its plain meaning that “avoids a strict numerical boundary to the specified parameter.” *Cohesive Technologies*, 543 F.3d at 1368.

Next, the ’952 Patent specification supports broader ranges of cyclophosphamide than the 12-23% claimed and, in fact, describes preferred and most preferred amounts of 5-40% and 6-30%, respectively. J.A. 3, col. 3, l. 48–col. 4, l. 5. Examples 2 and 6 are formulations of the invention that contain 12.01% and 22.62%, respectively, of cyclophosphamide based on total formulation weight. Example 1 discloses a claimed formulation having 10.71% cyclophosphamide. Therefore, the disclosure in the specification of cyclophosphamide formulations wherein the amount of cyclophosphamide is not limited to the strict range of 12-23%, and this disclosure is consistent with the claimed use of “about” in referencing cyclophosphamide.

Lastly, nothing in the prosecution history that limits the plain meaning of cyclophosphamide in a concentration “of about 12% to about 23%” to the strict numerical endpoints that are recited. On January 5, 2021, applicants conducted an interview with the examiner and discussed a range of 12%-25% by weight of cyclophosphamide. At the interview, the examiner expressed her view that the upper end of the range may not have adequate support in the patent specification, but those claims were never submitted and were never considered on the merits (or rejected). J.A. 523. Applicants added the weight range of cyclophosphamide of “about 12%-about 23%” for the first time on January 15, 2021. J.A. 525. During the interview on January 5, 2021, the examiner stated that cyclophosphamide amounts above 23%

would be within the scope of a claim reciting that endpoint, stating, “For example, the upper limit of cyclophosphamide disclosed in the specific examples of the Specification is 23.25%, 22.62%, 22.52%, which could be interpreted as approx. 23%. J.A. 523. This indicates that the examiner understood “about” to mean approximately and understood amounts of cyclophosphamide above 23% to be included within a claim reciting 23% as a numerical endpoint. In sum, Nexus does not meet the “exacting” standard required for disavowal/disclaimer because nowhere did applicants state that the invention does not include formulations with a cyclophosphamide content below 12% or above 23%, nor does the claim amendment by itself demonstrate a clear and unmistakable disavowal.

Again, the claim language, specification, and prosecution history does not compel a deviation from the ordinary meaning of the word “about” and the Court gives the term “about” its ordinary meaning of “approximately.” *See Merck & Co. v. Teva Pharmas. USA, Inc.*, 395 F.3d 1364, 1369–72 & n. 7 (Fed.Cir.2005). Accordingly, the Court construes “cyclophosphamide in a concentration of about 12% to about 23%” as “cyclophosphamide in a concentration of approximately 12% to approximately 23%”.

3. “stable”

The parties proposed constructions are summarized in the chart below.

Term	Nexus’s Proposed Construction	Plaintiffs’ Proposed Construction
“stable”	Indefinite	No construction necessary.

Plaintiffs contend that the term “stable” is in the preamble of the claim and therefore does not require construction as it is not limiting. The Court disagrees.

“Whether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.” *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003). When a patentee relies on language in the preamble in its arguments to obtain the patent at the USPTO, it cannot turn around and argue that the preamble has no patentable weight for purposes of showing infringement. *See Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381 (Fed. Cir. 2021) (“repeatedly reject[ing] efforts to twist claims, like a nose of wax, in one way to avoid invalidity and another to find infringement”) (cleaned up). Here, the prosecution history has numerous rejections by the examiner for obviousness over the prior art, and argument by the applicants that the claimed invention possessed unexpected stability over the prior art. *See J.A. 377–84; J.A. 385–92; J.A. 451–55; J.A. 456–60; J.A. 533–37*. The prosecution history also shows that the distinguishing feature of Plaintiffs’ claimed invention over the prior art was unexpected stability, which was argued extensively at the USPTO, and ultimately led to the allowance of the ’952 patent. *See J.A. 552–63*. The Federal Circuit has “held that where the preamble is relied on to distinguish the prior art during prosecution, it cannot later be argued that the preamble has no weight.” *Data Engine Techs.*, 10 F.4th at 1381 (citing *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1347–48 (Fed. Cir. 2002)). Thus, the Court agrees with Nexus that the term “stable” should be construed.

Nexus’s sole position regarding claim construction of the term “stable” is that it is indefinite. “A patent is invalid for indefiniteness if its claims, read in light of the

specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). To determine indefiniteness, courts examine “the patent record—the claims, specification, and prosecution history—to ascertain if they convey to one of skill in the art with reasonable certainty the scope of the invention claimed.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g., Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017). “Any fact critical to a holding on indefiniteness … must be proven by the challenger by clear and convincing evidence.” *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003).

Here, Nexus’s arguments repeatedly mention what a “person of ordinary skill in the art” would know, expect, or understand, but there is no evidence indicating who this person is, their education level and skills, and how they would view the patent disclosure. [51] at 15–18; *Lifescan Scotland, Ltd. v. Shasta Techs., LLC*, No. 11-CV-04494-WHO, 2014 WL 11206411, at *3 (N.D. Cal. Nov. 10, 2014) (“where extrinsic evidence of the perspective of someone skilled in the art is relevant to the indefiniteness inquiry, it is appropriate to defer the indefiniteness determination until after the close of discovery”). Given the stage of discovery and burden of proof, the Court finds it appropriate to defer consideration of Nexus’s indefiniteness

assertion until a later stage in the litigation. *See DuraSystems Barriers Inc. v. Van-Packer Co.*, No. 19-CV-1388, 2021 WL 4037826, at *6 (C.D. Ill. Sept. 3, 2021) (deferring consideration of “claim terms attacked as indefinite … until the summary judgment stage”); *0912139 B.C. Ltd. v. Rampion USA Inc.*, No. C18-1464JLR, 2019 WL 3426058, at *16 (W.D. Wash. July 30, 2019) (“district courts frequently decline to rule on indefiniteness at the *Markman* stage”) (collecting cases).

II. Motion for Judgment on the Pleadings

A. Legal Standard

Federal Rule of Civil Procedure 12(c) provides that after “the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings.” Courts apply the same standard in deciding a motion for judgment on the pleadings as they do in deciding a motion to dismiss. *Landmark Am. Ins. Co. v. Hilger*, 838 F.3d 821, 824 (7th Cir. 2016). The facts are viewed in the light most favorable to the non-movant. *Id.* To survive a motion to dismiss or for judgment on the pleadings, the challenged pleading must “contain sufficient factual matter, accepted as true, ‘to state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2009)).

B. Analysis

“Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). To satisfy the elements of inequitable conduct at the pleadings stage, a defendant must allege that the patent applicant “(1) made

an affirmative misrepresentation of fact, submitted false material information, or failed to disclose material information; and (2) intended to deceive the [Patent and Trademark Office (“PTO”).]” *CIVIX-DDI, LLC v. Hotels.com, L.P.*, 711 F. Supp. 2d 839, 843 (N.D. Ill. 2010) (citing *Rentrop v. Spectranetics Corp.*, 550 F.3d 1112, 1119 (Fed. Cir. 2008); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1314 (Fed. Cir. 2008)). Thus, a patent applicant engages in inequitable conduct if they “misrepresented or omitted *material* information with the specific *intent* to deceive the PTO.” *Therasense*, 649 F.3d at 1287 (emphases added).

“[T]o plead the circumstances of inequitable conduct with the requisite particularity under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). While “‘knowledge’ and ‘intent’ may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.* at 1328–29.

Nexus alleges four misrepresentations to the PTO: (1) applicant’s first declarations “compar[ed] a formulation that was not even disclosed in their application to allegedly show unexpected results over selected examples from the prior art”; (2) applicant’s second declarations “improperly used data from

compositions outside the claimed ranges to show unexpected results”; (3) “the applicant [] improperly claim[ed] a broader range than that described in the patent application”; and (4) applicant’s third declarations “did not compare the claimed invention to the closest prior art as is required to show unexpected results.” [41] ¶¶ 52, 58. The Court addresses each alleged misrepresentation in turn.

1. First Declarations

Nexus alleges that it was a material misrepresentation for the inventors’ first declarations to have compared “a formulation not covered by the application to the prior art in an attempt to show unexpected stability.” [41] ¶ 58. The declarations submitted in October 2019 by co-inventors Banda Nagaraju and Kocherlakota Chandrashekhar compared the performance of the following formulation of the invention (“Batch No. 195”) to the performance of the formulations in the Alam, Palepu, and Fragale (US 2013/0172271) prior art references:

S. No	Ref batch number: 195		
	Ingredients	Qty(mg) /mL	% (w/w)
1	Cyclophosphamide	200.000	22.3
2	Absolute Ethanol	620.000	69.2
3	PEG-400	34	3.8
4	Propylene glycol	34	3.8
5	Mono thioglycerol	0.138	0.015

[42-7] at 2 (Chandrashekhar Decl.); [42-8] at 2 (Nagaraju Decl.). The formulation of the invention, Batch No. 195, was within the ranges of the most preferred embodiment of the invention disclosed in the ’507 Application’s specification reciting cyclophosphamide in a range of (6-30%), ethanol in a range of (40%-92%), PEG-400 and PG each in ranges of (0%-15%) and monothioglycerol (< 3%) and was also within

the ranges of the then-pending claims. [1-1] at 3:59–4:4; [42-12] (October 2019 Amendment). Thus, Nexus concedes in its response that the first declarations compared the alleged invention to the prior art. [60] at 5.

Nevertheless, Nexus contends that the comparison was presented in a “confusing and misleading manner” in an “attempt to confuse the examiner.” [60] at 5–6. Even if this were true, confusion is not sufficient to support a credible allegation of a material misrepresentation of fact or omission with the intent to deceive the Patent Office. *Nevro Corp. v. Bos. Sci. Corp.*, No. 16-CV-06830-VC, 2017 WL 7795778, at *1 (N.D. Cal. Oct. 4, 2017) (“while an inventor must disclose all material information to the patent examiner, he is not required to make sure the patent examiner understands that information.”) (citing *Rothman v. Target Corp.*, 556 F.3d 1310, 1328–29 (Fed. Cir. 2009) (“While the law prohibits genuine misrepresentations of material fact, a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct.”)). In sum, Nexus fails to allege any affirmative misrepresentation of material fact or omission. See *Juicy Whip v. Orange Bang*, 292 F.3d 728, 745 (Fed. Cir. 2002) (“Whether the statements in the Bowers declaration were false or misleading is irrelevant to our inquiry, however, because Orange Bang failed to present any evidence that the Strattons knew or considered the Bowers declaration to contain anything untrue or that the declaration was submitted with any intent to mislead the examiner.”).

2. Second Declarations

Nexus next alleges that “it was a material misrepresentation when the second inventors’ declarations attempted to show unexpected results by comparing a formulation not within the claimed ranges to the prior art in an attempt to show unexpected results.” [41] ¶ 58. The inventors’ declarations of April 8, 2020, presented comparative studies focused on the effects on stability of different formulations when varying the ratios of PEG and PG, as well as ethanol concentration. The declarations state that these comparisons are “comparative studies.” [42-9] at 3 (Chandrashekhar Decl.); [42-10] at 3 (Nagaraju Decl.); *see also* Manual of Patent Examination Procedure (“MPEP”) 716.02(d)(II) (“To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range.” (citing *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960)). Specifically, formulations having PEG:PG ratios and ethanol concentrations outside of the claimed ranges (tables 1, 3) were compared to both (i) formulations having ethanol concentrations and PEG:PG ratios within the claimed ranges and (ii) formulations having ethanol concentrations within the claimed range but PEG:PG ratios outside the claimed range (tables 4 and 5). [42-9] at 1–4 (Chandrashekhar Decl.); [42-10] at 1–4 (Nagaraju Decl.).

Nexus highlights that the comparison formulations are presented in percentage by volume of the amount of total solvents used, while the then-pending claims expressed the amount of the various ingredients and solvents by ratio or as a

percentage of total formulation weight. [60] at 6. For example, Table 1 from the second declarations was a percentage of the solvents, not total formulation weight:

Ingredients	Quantity (%)		
	A	B	C
PEG-400	18	16	14
Propylene glycol	72	64	56
Ethanol	10	20	30

[42-9] at 2 (Chandrashekhar Decl.); [42-10] at 2 (Nagaraju Decl.). Similarly, Nexus notes that Tables 4 and 5 expressed the formulations as ratios of solvents instead of by total formulation weight:

Table 4: Stability details of Instant Application with varying ratios of PEG and PG (1:1, 1:2, 2:1) with and without MTG.

3 week at 40°C 75%RH									
PG:PEG	1:1 ratio			1:2 ratio			2:1 ratio		
PG:PEG	1.25:1.25;	5:5;	12.5:12.5;	0.83:1.67;	3.33:6.67;	6.67:13.33;	1.97:3.83;	6.67:3.33;	16.67:8.33;
:Ethanol	97.5	90	75	97.5	90	75	97.5	90	75
Without MTG									
Assay-Initial	100.3	100.8	101.7	104.2	101.4	98.2	102.1	102.3	99.8
Assay-1week*	98.7	98.2	98.2	101.6	99.2	96	103.1	99.5	97.7
Total Impurities	3.77	2.93	3.58	3.38	3.13	3.42	2.88	3.18	3.32
Drop in assay	1.6	2.6	3.5	2.6	2.2	2.2	2.0	3.4	2.1
With MTG									
Assay-Initial	99.5	100.4	98.1	100.2	99.3	98.6	100.5	100.3	98.6
Assay-1week*	97.8	97.1	95.1	97.2	97.3	95.3	97.5	98.6	95.1
Total Impurities	3.48	3.85	3.86	2.65	3.33	3.42	2.95	3.43	3.91
Drop in assay	1.8	3.3	3.0	3.0	1.8	3.3	3.0	3.4	3.5

[42-9] at 3 (Chandrashekhar Decl.); [42-10] at 3 (Nagaraju Decl.). Thus, Nexus alleges that the Applicant's submission "appears to be an attempt to mislead or deceive the patent office." [41] ¶ 34. To put it another way, Nexus asserts that the second declarations compared apples to oranges. [60] at 7. However, like the first declarations, Nexus does not point to any misrepresentations of fact by Plaintiffs and

allegations that data is confusing does not suffice. *Nevro Corp.*, 2017 WL 7795778, at *1; *Rothman*, 556 F.3d at 1328–29.

3. Applicants' Claimed Ranges of Amounts of the Formulation Ingredients

Nexus alleges that the applicant misled the examiner by improperly attempting to recite a range of ingredient amounts in the claims that was broader than the ingredient ranges described in the '507 Application. [41] ¶¶ 36, 52. In a March 23, 2021 interview, the examiner stated that “some of the ranges in new claims 46, 47, 48, 50 and 51, submitted on 15 January 2021, do not find support in the Specification as filed.” [43-5] at 9. In response, the applicant’s prosecuting attorney amended the claims, as allowed by the patent examiner. *Id.* at 3. Here, the applicants amended a claim after a discussion with the examiner about claim scope. *See Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307–08 (D. Del. 2013) (“[A]mending a claim, on its face, does not constitute an affirmative misrepresentation before the PTO.”). Again, Nexus has failed to allege a misrepresentation or omission and the allegations do not support fraudulent intent. *See Impact Engine, Inc. v. Google LLC*, No. 319CV01301CABBGS, 2020 WL 3414627, at *2 (S.D. Cal. June 22, 2020) (“Without some allegation of misrepresented fact or material omission in the written description made or withheld to allow the claims to issue, there is no fraud.”).

4. Comparisons to the “Closest Prior Art”

Finally, Nexus alleges that the applicant did not compare the claimed invention to the closest prior art as is required to show unexpected results, that “went unnoticed” by the examiner, and that “the inventors tried to sneak anything they

could by the examiner.” [41] ¶¶ 52, 59. The examiner stated in a December 31, 2019, Office Action that “the examiner’s position is that the closest prior art is Alam.” [42-18] at 3. The examiner confirmed her views in a September 15, 2020, Office Action, stating, “[t]he examiner acknowledges that the data in table 1 (stabilities in table 3) corresponds to formulations taught by Alam, which were identified by the examiner [] as the closest prior art.” [42-19] at 3. When allowing the claims, the examiner stated, “[t]he examiner notes that the closest cited prior art by Palepu and Alam teach compositions comprising cyclophosphamide dissolved in ethanol ...” and that applicant had shown in a side-by-side comparison better stability with the claimed formulation as compared with the prior art formulations of Alam and Palepu. [42-6] at 2, 6. Additionally, Nexus cites no authority requiring applicants to affirmatively point out specific portions of an examiner-cited reference of record believed to be more relevant than the examiner’s cited portion thereof. *See MPEP 716.02(e)(I)* (“Applicants *may* compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner.” (emphasis added)). Overall, the examiner stated at least three times that Alam (and later Palepu) were the closest prior art and the applicant submitted three declarations comparing the claimed formulations to Alam and Palepu. Thus, Nexus’s allegations are insufficient because they are contradicted by the examiner’s statements demonstrating the applicant compared the claimed formulation to the examiner-selected closest prior art. *See Astrazeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583

F.3d 766, 775 (Fed. Cir. 2009) (finding that the examiner's acceptance of applicant's closest prior art comparison was not a material misrepresentation).

CONCLUSION

For the stated reasons, the Court adopts the constructions identified above, defers consideration of the claim term Defendant asserts is indefinite, and grants Plaintiffs' motion for judgment on the pleadings [43]. Nexus's counterclaim is dismissed with prejudice.

E N T E R:

Dated: July 31, 2024



MARY M. ROWLAND
United States District Judge